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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,477	01/09/2007	Masao Sudoh	Q94121	2361
23373 7590 11/19/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER KATAKAM, SUDHAKAR				
ART UNIT		PAPER NUMBER		
1621				
NOTIFICATION DATE		DELIVERY MODE		
11/19/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
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### Office Action Summary

**Application No.**

10/574,477

**Applicant(s)**

SUDOH ET AL.

**Examiner**

SUDHAKAR KATAKAM

**Art Unit**

1621

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5, 7-16, 18, 19, 23-31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 18, 19 and 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7-16, 23-28, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Status of the application*

1. Receipt of Applicant's remarks and arguments filed on 13 July 2009 is acknowledged.
2. With regard to the 103(a) rejection, the applicants' arguments are not found persuasive and as such the previous rejection made on 12 Feb 2009 has been maintained.

### *Response to Arguments*

3. Applicant's arguments filed on 13 July 2009 have been fully considered but they are not persuasive.

*The examiner acknowledges applicants argument that there is no description in **Black** at all of sodium phosphate and stabilization.*

The examiner contends, however, that **Black** do teach use of phosphate buffer saline solution as a carrier for the bradykinin, comprises 10-40 micrograms/mL of bradykinin and 0.09% phosphate buffered saline solution [col. 5, lines 41-45]. Please note that the purpose of buffer is to stabilize the components in it.

*The examiner acknowledges applicants argument that applicants solved the clouding problems of (2R)-2-propyloctanoic acid with their buffer conditions.*

The examiner contends, however, that the solubility and stabilization depends on the buffering conditions of the solvent. For example, **Takada et al** teach a process to improve the solubility of the drug compound and thereby providing a solution thereof and some kinds of drug products using the solution, moreover providing a solution of

higher concentration and a high-dosage drug product using the solution, and in order to improve the solubility of drug compounds, which can be accomplished by adding at least one pH adjuster selected from tri-sodium phosphate, a hydrate thereof, sodium hydroxide or potassium hydroxide to the solution [see 0008 - 0010]. Therefore, applicants claimed advantages are expected results.

*The examiner acknowledges applicants argument that **Hasegawa et al**, **Hisao et al** and **Ohuchida et al** do not even recognize the problem solved by applicants.*

The examiner contends, however, that the purpose of first two references to show the optically active (R)-2-propyloctanoic acid and its use in treatment of neurodegenerative disorders. **Ohuchida et al** teach suitable basic metal ions for the preparation of salts of pentanoic acid derivatives, which relevant to applicants' compound and its stability.

So, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made, with the teachings of the cited reference to make applicants' claimed medicament with a reasonable expectation of success, since it is within the scope to optimize the conditions through a routine experimentation.

#### **Claim Rejections - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-3, 5, 7-16, 23-28, and 33-34 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **Hasegawa et al** (Bull.Chem.Soc.Jpn. 2000, 73, 423-428) or **JP 8291106** in view of **Ohuchida et al** (US 6,201,021), **Black** (US 6,043,223), **Toda et al** (US 6,608,221) and **Takada et al** (US 2002/0022738 A1) for the reasons of record as set forth in the office action on 2/12/09.

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Conclusion***

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/  
Examiner, Art Unit 1621

/Peter G O'Sullivan/  
Primary Examiner, Art Unit 1621